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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,953	12/10/1998	OYSTEIN FODSTAD	7885.56USWO	8358

7590 02/27/2002  
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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/27/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/125,953

Applicant(s)

FODSTAD ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,5-9 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-9 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 3, 5-9 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Upon review of the disclosure it is noted that in none of the experiments provided (Examples 1-4 at pages 5-7 of the specification) that none of the reaction conditions are set forth. At page 6, first paragraph, it is noted that reference has been made to certain journal articles as to how differential display was conducted. At page 4, last paragraph, reference has been made to a PCT publication as disclosing methods for the positive selection of target tumor cells. Further review of the specification fails to find any indication that the articles had been incorporated by reference. Assuming *arguendo*, that the articles had been incorporated by reference, the present specification would not satisfy the requirements of enablement as set forth under 35 USC 112, first paragraph, as the incorporation by reference of essential subject matter without such subject matter being in a cited US patent is prohibited. Accordingly, the subject specification is essentially silent as to what reaction conditions and starting materials are used in practicing the full scope of the claimed methods. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

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“ ‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’).

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“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (emphasis added)

3. Claim 2 further defines claim 12 as allowing the simultaneous screening of 12 or more different samples. The specification clearly does not present such a showing and as such, the

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specification does not enable the identification of one or more genes when the starting can be in a cell and/or be a mixture of nucleic acids from a variety of tissues.

4. Claims 2, 3, 7-9 and 12 have sufficient breadth of scope so to encompass conducting the assay either *in vivo* or *in situ*. In support of this position, attention is directed to claims 5 and 6 which further limit the method of claim 12 to where RNA and DNA is isolated from the cells. Attention is also directed to applicant's traversal of the objection of claim 5 in that the aspect of isolating RNA and DNA from cells further limits claim 12. In applying such logic, it stands to reason that the method is to be practiced without such isolation of RNA and DNA from any isolated cell. The specification provides four examples with examples 2-3 being built upon that of Example 1. As set forth in Example 1, RNA was first extracted from the immunomagnetically-separated cells (one pass). Applicant is seemingly relying upon one of skill in the art to determine how such embodiments are to be practiced. Such reliance upon the public for enablement, and not that of the specification, is an unfair shifting in the duty of full and complete disclosure as to how one is to make and use the claimed invention.

5. Claim 9, which depends from claim 8, is not enabled by the disclosure as it relates to studying the pattern of expression for the "identified genes." It is noted that the subject disclosure does not set forth a repeatable procedure whereby any gene has actually been identified and is subsequently studied. Without something to guide the skilled artisan, the skilled artisan must resort to undue experimentation to practice the claimed invention.

6. While applicant, in their response of 05 November 2001, asserts that one of skill in the art would be able to practice the invention of Claim 9 by applying "well-known techniques," said argument has not been found persuasive. It is noted that applicant has not disclosed in the

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specification nor provided via their argument, an indication of just which prior teachings would fully enable the claimed invention of claim 9. At page 4 of the response of 05 November 2001 it is asserted: "The successes of the claimed method were not contemplated, or even conceivable, prior to the filing of the present application." It stands to reason, therefore, that if the invention was so inconceivable, the same public would not now be able to apply prior art teachings to now fully enable the same inconceivable method. Yet, applicant's argument would have one believe that the same ignorant public can now do the impossible.

7. For the above reasons, and in the absence of convincing evidence to the contrary, the subject specification has not been found to enable the claimed invention and as such, claims 2, 3, 5-9 and 12 remain rejected under 35 USC 112, first paragraph.

### ***Conclusion***

8. Rejections and/or objections which appeared in the prior Office action and which were not repeated hereinabove have been withdrawn.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

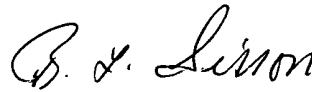
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

bls  
February 24, 2002